Significant Analysis
Sections -201, -520 and -635 of Chapter 246-101
Washington Administrative Code (WAC)

Briefly describe the proposed rule.

Retain Asymptomatic HIV Case Reports by Name and Expand HIV Laboratory Test Reporting

This proposed rule revision:
- Expands current HIV laboratory test reporting to include all HIV laboratory test results;
- Permits local health jurisdictions (LHJs) to retain names of asymptomatic HIV cases;
- Requires Department of Health (Department) to retain names of asymptomatic HIV cases; and
- Requires a report, due by December 2007 to the State Board of Health on impacts of the rule change.

Expand current HIV laboratory test reporting to include all HIV laboratory tests
WAC 246-101-201 *Notifiable conditions and laboratories*
This section describes notifiable conditions that Washington laboratories report to public health authorities statewide. The proposed rule revision removes the required percentages or values of HIV laboratory tests for the test results to be reported to the Department. This revised language would require all HIV laboratory tests be reported to the Department.

Permit LHJs to retain names of asymptomatic HIV cases
WAC 246-101-520 *Special conditions -- AIDS and HIV*
This revised section permits local name retention of asymptomatic HIV cases and describes the security and confidentiality standards consistent with the Centers for Disease Control and Prevention (CDC) 2006 Security and Confidentiality Guidelines that must be followed for an LHJ to retain asymptomatic HIV case reports by name.

The Department will perform a biennial review of the system security measures for local health jurisdictions that retain asymptomatic case reports by name.

Local health officials will report HIV cases to the Department and assist the Department in reascertaining (replace coded identifiers with names) the identities of previously reported cases of asymptomatic HIV infection.

Require the Department to retain names of asymptomatic HIV cases
WAC 246-101-635 *Special condidiitions -- AIDS and HIV*
This revised section requires the department to retain asymptomatic HIV cases by name solely for the purpose of complying with the CDC's HIV reporting requirements. This revised section describes the security and confidentiality standards consistent with the CDC's 2006 Security and Confidentiality Guidelines that must be followed by the Department to retain asymptomatic HIV case reports by name.

The state health officer or designee must conduct a biennial review of the system security measures at local health jurisdictions that are maintaning HIV case records by name.

A report is due by December 2007 to the State Board of Health
WAC 246-101-635 *Special condiditions -- AIDS and HIV*
The state health officer in cooperation with the local health officers will provide a report to the State Board of Health detailing; a) ability of the HIV reporting system to meet surveillance performance standards established by CDC; b) cost of the reporting system to state and local departments; c) reporting systems effect on disease control activities; d) impact of HIV reporting on HIV testing among at-risk persons; and e) availability of anonymous testing in the state.

Is a Significant Analysis required for this rule?

Yes. The Department of Health has determined that significant analysis is required for the following sections of chapter 246-101 WAC:

-201, Table Lab-1 (Conditions Notifiable by Laboratory Directors) Human immunodeficiency virus (HIV) infection;
-520, subsections (1)(a)(v), (1)(b), (1)(c), (4), (7);
-635, subsections (6), (7), (8), (9),(10), (11).

The Department of Health has determined that no significant analysis is required for the rest of the proposed rule changes as they do not:

- adopt substantive provisions of law pursuant to delegated legislative authority, the violation of which subjects a violator of such rule to a penalty or sanction;
- establish, alter, or revoke any qualification or standard for the issuance, suspension, or revocation of a license or permit; or
- adopt a new, or make significant amendments to, a policy or regulatory program, and therefore do not qualify as a significant legislative rule change.

All other revisions are considered housekeeping.

A. Clearly state in detail the general goals and specific objectives of the statute that the rule implements.

The general goal of chapter 70.24 of the Revised Code of Washington is to control and treat sexually transmitted disease (STD's). In subsection 70.24.125 of this chapter, the Board is given specific responsibility to establish reporting requirements for sexually transmitted diseases. In subsection 70.24.105 (1) (c), the legislature authorized the release of identifying information to the CDC "in accordance with reporting requirements for a diagnosed case of a sexually transmitted disease."

As the CDC will only accept HIV data from states with name-based retention systems and recommends expanded laboratory reporting, these proposed rules meet the legislative intent of chapter 70.24 of the Revised Code of Washington.

In RCW 70.24.400, the legislature directed the Department to provide funding for disease control services. Local retention of names is the most efficient and streamlined

manner to carry out these disease control mandates, and is consistent with all other communicable disease reporting practices.

B. Determine that the rule is needed to achieve these goals and objectives, and analyze alternatives to rulemaking and the consequences of not adopting the rule.

Yes, the proposed rule revisions are necessary to expand HIV laboratory test reporting and for the name retention of asymptomatic HIV case reports.

Expand current HIV laboratory test reporting to include all HIV laboratory tests

The recommended use of HIV laboratory test reporting has changed over time to reflect current medical technology and its benefit to surveillance in directing HIV/AIDS prevention and care activities. The Council of State and Territorial Epidemiologists (CSTE) and the CDC recommend that states require reporting of all HIV laboratory test results (CD4s, viral loads). The proposed revision will allow a more accurate portrayal of our state epidemic and decrease the need for lab personnel to sort test results by value for reporting.

Require the Department to retain by name asymptomatic HIV case reports

The CDC sent three letters between September and December 2005, two to the Department and one to Governor Gregoire's Office, which clearly state CDC policy to accept HIV case reports only from states with a confidential name-based surveillance system. The letter to Governor Gregoire's office states, *"Data from non-name based systems cannot be included into counts for the* [Ryan White CARE Act funding] *formulas. Therefore, states that use non-name based systems are at risk for losing federal dollars."*

In Fiscal Year 2007, Federal Ryan White CARE Act (RWCA) funding will be calculated on the proportion of states' HIV cases reported to CDC. This proposed revision is necessary to enable DOH to convert to a confidential name-based retention system and maintain federal RWCA care funding.

RWCA funding is allocated to states through the US Department of Health and Human Services, Health Resources and Services Administration (HRSA). This funding supports HIV case management, anti-HIV treatment regimens and HIV specific medical care for individuals living with HIV/AIDS in Washington State.

Permit local health jurisdictions to retain asymptomatic HIV case reports by name

The proposed revision would allow LHJs to retain asymptomatic HIV case reports by name. The CDC communications did not specifically mention name retention at the local level for our system to be in compliance with HIV reporting requirements. Local health departments have retained AIDS case reports by name since 1984; no known or reported breaches have occurred to date.

- Local health department personnel perform disease investigation and partner counseling and referral activities. Name retention at the local level will allow

LHJs to collect complete, accurate and timely data and to understand the local epidemic.

Alternatives to rulemaking:
Alternatives to rulemaking were not identified. Rule must be revised to expand HIV laboratory test reporting and retain asymptomatic HIV case reports by name in order to meet CDC reporting requirements This proposed rule revision meets CDC's laboratory reporting recommendation and HIV case reporting requirement thus, meeting the legislative intent of chapter 70.24 RCW. While local name retention is not specifically mentioned in CDC's HIV reporting requirement, this proposed revision meets the legislative intent of RCW 70.24.400, wherein the legislature directed the Department to provide funding for disease control services.

Consequences of not adopting the proposed rule:

- A state HIV/AIDS surveillance system that is not able to accurately and effectively portray the epidemic and identify HIV care and prevention service gaps that guide funding decisions.
- An estimated $3 million to $5 million funding decrease annually in HIV care, compromising both individual and community health.
- A less efficient local HIV reporting system that has to rely more upon assistance from the Department to perform necessary disease control and data collection activities.

C. Determine that the probable benefits of the rule are greater than its probable costs, taking into account both the qualitative and quantitative benefits and costs and the specific directives of the statute being implemented.

The portions of the rule that are significant are analyzed in the numbered list below. As discussed above, other portions of the rule are not significant and are therefore not included in this analysis.

1. Expand current HIV laboratory test reporting to include all HIV laboratory tests.

Description:
This proposed revision would expand current HIV laboratory reporting to include all HIV laboratory test results, not just those with a specific value. In 1995, Washington began reporting CD4 T lymphocytes (CD4) test results of <200 or 14% (of total lymphocytes). Viral load reporting (results above undetectable) was part of the September 1999 rule change that established our current name-to-code HIV reporting system. CD4s are a marker of immunologic function and are medically monitored along with viral load to follow HIV disease progression.

The treatment of disease has evolved in the past decade. The use of antiretrovirals in 1995 to treat HIV has slowed the progression of disease from HIV to AIDS and from AIDS to death. There are more individuals living with HIV/AIDS in Washington State than at any other time. Additionally, the number of places people receive HIV care has expanded. In the past, a limited number of key physicians treated individuals with HIV/AIDS and made diagnoses based on clinical conditions. Medical care for HIV has become more decentralized, and diagnoses are made based on lab results. In Washington, approximately 75 percent of newly diagnosed cases of HIV come to the

attention of the surveillance system via laboratory reporting. A much smaller proportion are reported by health care providers.

At this time, laboratory reporting in Washington State is incomplete because it is not comprehensive. While the current system detects individuals who are more advanced in their disease process (CD4s <200 or detectable viral loads), it misses those who are doing well because they are early in the course of their infection, receiving treatment for their HIV, or both.

Probable Benefit:
Receiving comprehensive lab results will allow the Department to have more complete reporting of disease. It will also allow for better estimation of those who are not in care, as defined as not having received a viral load test, CD4 test, or antiretroviral therapy in the previous 12 months. At this time, people whose lab results are not reported may be doing well clinically (have undetectable viral loads or high CD4 counts), but from the perspective of the surveillance system, they meet the definition of "not in care" because their lab values are not reportable. Comprehensive lab reporting will allow the Department to better distinguish between these two groups and more accurately target resources.

Laboratory testing plays a critical role in health assessment, health care, and public health. Test results contribute to diagnosis and prognosis of disease, monitoring of treatment and health status, and population screening for disease.

Reporting of comprehensive laboratory data offers many opportunities to enhance the quality of HIV/AIDS surveillance information. HIV and HIV-related laboratory test results can be used to:

- identify cases;
- mark access to care and treatment;
- determine the stage of the disease;
- measure unmet health care needs among HIV-infected persons; and
- evaluate HIV testing and screening activities.[1]

CSTE and CDC recommend expanding HIV laboratory reporting to include all HIV related laboratory test results. This proposed rule meets the legislative intent of 70.24.125 to establish reporting requirements for sexually transmitted diseases.

Probable Cost:
This revision will decrease laboratory personnel time to sort laboratory test results for reporting. While there may be a temporary increase in workload to process lab results at the Department, there will be no associated cost.

2. Require the Department to retain by name asymptomatic HIV case reports.

Description:

[1] Centers for Disease Control and Prevention. Reported CD4+ T-lymphocyte results for adults and adolescents with HIV/AIDS – 33 states, 2005. HIV/AIDS Surveillance Supplemental Report 2005; 11 (No.2): [page 5]. Available at:http://www.cdc.gov/hiv/stats/hasrlink.htm.

The proposed revision is designed to protect public health by; 1) providing better data crucial to maintaining the availability of Washington's excellent care and treatment structure; 2) insuring compliance with federal HIV/AIDS reporting requirements; and 3) improving the quality of HIV/AIDS data that guide care and prevention funding decisions. This proposed revision responds to the intent of chapter 70.24 RCW, specifically section .105 (1) (c) authorizing the release of identifying information to the CDC "...in accordance with reporting requirement for the diagnosed case of a sexually transmitted disease." The CDC will only accept HIV data from a name-based retention system.

Because people with HIV are living longer, healthier lives, there is a greater likelihood that they will live in numerous places over the course of their lives. They will likely receive HIV care in all of these different places, and consequently be reported to the surveillance systems in all of these locations. CDC wants one unified method of reporting and maintaining data to exist across all reporting areas so that people who are reported to more than one surveillance system can be identified as such and not counted as two or more cases of disease when they actually represent one. This contributes to accurate enumeration of people with HIV at the national level and more equitable distribution of resources.

As described in Section B, HRSA, through the RWCA, will use the states' portion of HIV and AIDS cases (not just AIDS) in calculating funding allocations beginning Fiscal Year 2007. These HIV case data are derived from the national HIV/AIDS database that is maintained by the CDC. Washington's HIV case data are not accepted by the CDC into the national database because of our current name-to-code HIV reporting system. Since September 2005 the CDC has clarified its' position that only HIV case data from confidential name based systems will be included in the national database. A federal HIV care funding loss of $3 million to $5 million annually may result if Washington does not adopt a confidential name based HIV retention system.

Probable Benefit:
This revision will allow Washington to maintain the current HIV care and treatment structure that supports HIV case management services to 1,923 individuals in Washington.[2] Uninterrupted antiretroviral treatment and access to support services for HIV-positive persons improve overall health outcomes, both at the individual and community level. These services maintain the health and quality of life of individuals with HIV and those receiving care may have lower viral loads and be less likely to transmit disease, potentially reducing the burden of HIV on the community. Several studies indicate that uninterrupted access to antiretroviral therapy may decrease the sexual transmission of HIV and clinical trials already show that it significantly decreases mother to child HIV transmission.[3] The average lifetime cost of HIV care is estimated at $195,188 (1996 dollars).[4] The monthly cost for treating persons with HIV increases as CD4 counts decrease (indicating disease progression); the treatment cost per month for a person with a CD4 count below 200 is three times that of an individual

[2] 2004 CARE Act Data Report (CADR), 1/1/04 and 12/31/04.
[3] McClelland S, Baeten J. Reducing HIV-1 transmission through prevention strategies targeting HIV-1-seropositive individuals. Journal of Antimicrobial Chemotherapy, 2006 57(2):163-166.
[4] Cohen D, Wu S, Farley T. Comparing the Cost-Effectiveness of HIV Prevention Interventions. Journal Acquired Deficiency Syndrome, November 2004; 37:1404

with a CD4 count above 500.[5] Washington can decrease the community cost of treating HIV by sustaining necessary medical, treatment and support services that are currently available for individuals living with HIV/AIDS.

Washington's name-to-code HIV reporting system was established in September, 1999. Although this reporting system performs well on data completeness and accuracy, the CDC requires confidential name-based reporting for data to be included in the national database. While individual state systems that incorporate use of a code may perform well locally, states that are using codes are not using common codes, making it impossible to identify duplicate cases across state lines. Consequently, CDC is requiring that all states adopt name-based reporting systems. This revision will ensure that Washington's HIV/AIDS reporting complies with the CDC's reporting requirements and that all HIV and AIDS cases reported to CDC are included in the national database.

Probable Cost:
The largest anticipated financial cost will result if this proposed rule for the name retention of HIV case reports is not adopted. Also, there is a social cost that this rule revision will diminish the perceived confidentiality of those seeking HIV testing because a positive test result would be kept by name rather than coded identifier. Some HIV/AIDS advocates are concerned that a name retention system will be interpreted as an individual's name being reported to the national database (all HIV and AIDS cases are reported to the CDC by code, not name). Stakeholders and HIV/AIDS advocates are concerned that name retention of asymptomatic HIV case reports will decrease the number of individuals accessing confidential HIV testing and counseling. State and national data indicate that a states' HIV reporting system does not have a significant effect on whether an individual seeks HIV testing or not. This information is described on page 10, *Name Retention of Asymptomatic HIV Case Reports, Perceived Confidentiality and Impact on HIV Testing.*

Washington State receives approximately $11.2 million annually in Ryan White CARE Act funding for HIV care and treatment through;

- Title II Base receives almost $3 million to fund HIV support services; and
- AIDS Drug Assistance Program (ADAP) receives just over $8 million to fund HIV treatment.

Washington could lose an estimated $3 million to $5 million in federal Ryan White CARE Act Title II funding if the Department does not adopt rules to retain HIV case reports in a confidential name-based system. The Government Accountability Office (GAO) released a report in June 2005 describing their preliminary findings on the impact of the current RWCA provisions. These findings include estimated funding loss in states with a name-to-code or code-based reporting system. The report indicates that Washington State would experience a 38% reduction in Title II Base funding.[6]

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[5] Clay P. Examining the Pharmoeconomics of HIV Treatment. Presentation, Examining the Pharmacoeconomics of U.S. AIDS Drug Access, Washington, DC, April 6, 2004. Available at http://www.thebody.com/iapac/may04_suppl/treatment.html

[6] Government Accountability Office. Ryan White CARE Act, Factors that Impact HIV and AIDS Funding and Client Coverage. Testimony, June 23, 2005: Page 38. Available at http://www.gao.gov/new.items/d05841t.pdf.

Potential Title II Program Impacts Based on GAO's 2005 Report

Significant reductions in Title II funding would force the Department's HIV Client Services Section to prioritize HIV care services provided to HIV-positive individuals that access the program across the state. The top priority is to assure that HIV-positive individuals receive ongoing access to HIV-related medications. Secondary to this are support services designed to assist traditionally underserved individuals in obtaining and remaining in primary medical care and assistance with insurance premiums to maintain comprehensive health care.

Example 1: $3 Million Title II Reduction

Approximately $2.5 million distributed to 14 consortia throughout Washington would be eliminated (Title II Base funding). Through direct contracts and sub-contracting, 20 community based organizations (CBO's) are funded to provide HIV related care services. This funding supports essential services that assist HIV-positive individuals to obtain and remain in primary medical care including;

- case management;
- transportation;
- mental health and chemical dependency treatment;
- oral health;
- housing; and
- psychosocial support.

Of these services, case management receives 64% of Title II Base, or $1.5 million. Case management links nearly 2,000 HIV-positive individuals in Washington State with primary medical care and prevents unnecessary hospitalization. A majority of these individuals are traditionally underserved persons who are poor, have little or no health insurance, and live with multiple, complex needs. Without these support services, these individuals risk losing contact with ongoing medical care, increasing their chances of becoming non-compliant in their adherence to HIV-related medication and therefore reducing their life expectancy and increasing their infectiousness.

FFY 2005 consortia funding allocations (Title II Base): This list represents aggregate amounts allocated to all 14 consortia throughout the state that would be eliminated through the Example 1 reduction.

• Case Management	$1,551,250
• Client Advocacy	$143,572
• Emergency Financial Assistance	$76,532
• Food Bank/Home-Delivered Meals/Nutritional Supplements	$115,053
• Health Education/Risk Reduction	$4,444
• Housing Services	$52,440
• Housing-Related Services	$52,042
• Mental Health Services	$118,129
• Nutritional Counseling	$1,845
• Oral Health	$73,710
• Psychosocial Support Services	$20,890
• Substance Abuse Services	$4,555

- Transportation $31,043
- Treatment Adherence Services $32,812
- Other Support Services $29,759
- Outreach $3,890
- Consortia Support $112,234

Example 2: $5 Million Title II Reduction

The $2.5 million Title II Base funding detailed above for support services would be eliminated in this example. An additional $2.5 million would be removed from the ADAP in the form of additional program restrictions, decreased income limits, higher cost-sharing, additional formulary restrictions, enrollment waiting list, and limitations on insurance premium assistance. Currently, CBO's are the primary mechanism used by clients to assist them with eliminating the barriers to their care and access to much needed life-saving medications. The severe funding reduction described in this example could greatly impact the ability of some of these CBO's to continue providing RWCA support services. Without these agencies, if base funding were no longer available, individuals would not be able to access the medications they need to stay alive and healthy. Adherence to a prescribed regimen of antiretroviral treatment may be interrupted which could lead to a deterioration in a client's health.

Name Retention of Asymptomatic HIV Case Reports, Perceived Confidentiality and Impact on HIV Testing (This analysis applies to both Department and LHJ retention of asymptomatic HIV case reports by name.)

Data collected by the Department through the Supplement to HIV/AIDS Surveillance (SHAS) interview project and the HIV Testing Survey (HITS) suggest that individuals are not strongly influenced positively or negatively by the state's HIV reporting system when considering HIV testing. Nor does a name based reporting system result in a mistrust of government with confidential information.

The SHAS interview project asked respondents who represent a sample of persons reported with AIDS in Washington what reason they had for delayed HIV testing. Among 434 HIV-infected respondents, 21 percent cited fear of finding out they were HIV-positive, and 29 percent reported that they didn't think they were at risk or that they didn't think HIV could happen to them. Only 2 percent of respondents cited concern about discrimination and only 1 percent cited concerns about confidentiality. [7]

When Washington adopted the current name-to-code HIV reporting system in 1999, the Department participated in the CDC funded HITS in 2000, 2002 and 2003 to determine the impact of this type of reporting system on testing patterns among men who have sex with men (MSM), injection drug users (IDU) and high risk heterosexuals (HRH).

Between 2002 and 2003, 539 individuals participated in HITS. MSM and IDU's cited *unlikely sex risk* as the most common reason for not testing in the last 12 months. Other common reasons included, *thought they were HIV negative*, *afraid to find out*, or *didn't have time*. Only one individual cited worry about name being reported to the

[7] Courogen M. Timing of HIV testing among people with AIDS – SHAS interview project results. Washington State Responds, March/April 1999:21-25.

government. Over 65 percent of respondents did not know what type of HIV reporting methods were used in Washington State and only 13 percent reported name-to-code correctly. Twenty-three percent of all respondents answered yes to name or name-to-code system, and 28 percent thought HIV positive names are reported to the federal government. These respondents were not less likely than other respondents to have ever been tested.[8] HITS data from Washington State were consistent with HITS data collected nationally in previous years.

The Department and the Board are aware that this proposed revision may deter some individuals from initially seeking confidential HIV testing and take this concern seriously. The proposed revision to retain names includes security and confidentiality requirements consistent with the CDC's 2006 Security and Confidentiality Guidelines for LHJs and the Department to retain HIV case reports by name. This proposed rule does not require LHJs to maintain asymptomatic HIV case reports by name – only the Department. Washington State has maintained AIDS case reports by name since 1982 and there have never been any known or reported breaches to this system at the state or local level.

3. Permit local health jurisdictions to retain asymptomatic HIV case reports by name

Description:
This proposed revision responds to the intent of chapter 70.24 RCW, specifically section .400 that directs the Department to provide funding for disease control services. Local name retention is the most efficient manner to carry out these disease control mandates.

Name retention at the local level will allow LHJs to collect complete, accurate and timely data and to better understand the local epidemic. Washington's communities are very diverse, more urban in the northwest, I-5 corridor and largely rural throughout the remainder of the state. Local HIV data in addition to state data can further guide prevention and care decisions to ensure local needs are addressed.

Probable Benefit:
In recent years, federal prevention and care funding has remained flat or experienced small rescissions; this downward funding trend is expected to continue. Improving efficiency and accuracy is vital as resources diminish. The name retention of asymptomatic HIV case reports will improve follow up on disease investigation, streamline partner counseling and referral activities and simplify the linking of HIV with other disease registries for disease control purposes. **A single, confidential name-based reporting and retention system could increase efficiency, decrease the complexity of maintaining multiple systems and ensure that Washington is in compliance with CDC's reporting requirements at the local level.** Local name retention will benefit public health practice because it will:

- Allow better characterization of the epidemic at the local level;
- Decrease follow up on disease investigation;
- Streamline partner counseling and referral services;

[8] Rime T. HIV Testing Patterns for Persons at Risk for HIV: Results from the Washington State HIV Testing Survey, 2002-2003.

- Simplify the linking of HIV with other disease registries for disease control purposes.

Probable Cost:
There is no financial cost associated with this rule revision because LHJs are not required to maintain asymptomatic HIV case reports by name. They are only required to follow the proposed rule if they choose name retention. There is a social cost that this rule revision will diminish the perceived confidentiality of those seeking HIV testing because a positive test result would be kept by name rather than coded identifier. This information is described on page 10, *Name Retention of Asymptomatic HIV Case Reports, Perceived Confidentiality and Impact on HIV Testing.*

4. ***Provide a report to the State Board of Health by December 2007 on the name reporting system and availability of anonymous testing.***

The state health officer in cooperation with the local health officers will provide a report to the State Board of Health by December 2007 on: a) the ability of the HIV reporting system to meet surveillance performance standards established by CDC; b) the cost of the reporting system to state and local departments; c) the reporting system's effect on disease control activities; d) the impact of HIV reporting on HIV testing among at-risk persons; and e) the availability of anonymous testing in the state.

There is no cost associated with this report. The availability of anonymous testing remains a key issue in the Department's work with community stakeholders for this proposed WAC revision. Stakeholders and advocates want to ensure the availability of anonymous testing across the state as an alternative means of HIV testing. There are concerns that name retention of asymptomatic HIV case reports will decrease the number of individuals accessing confidential HIV testing and counseling. Lifelong AIDS Alliance and other community-based, AIDS service organizations provided written feedback and proposed amendments to the *Draft 2 of Proposed Permanent Rule Changes*. Stakeholders suggested the addition of "availability of anonymous testing" to the report requirements. The Department has included this suggestion in the proposed WAC revision language.

D. Determine, after considering alternative versions of the rule, that the rule being adopted is the least burdensome alternative for those required to comply with it that will achieve the general goals and specific objectives stated previously.

Department staff worked closely with constituents and the public to minimize the burden of this rule and to establish language that would achieve the goals and objectives of the authorizing statute, chapter70.24 RCW.

Department staff published alternative versions of the proposed revisions on the web (Draft #1 and Draft #2); conducted a series of publicized stakeholder meetings across the state to gather public input; and, solicited additional comments through several venues including email, postal mail and telephone.

Public comment was gathered and considered on both drafts. Because of public input, elements of this draft were accepted while other elements were rejected and/or amended in further drafts.

Expand current HIV laboratory test reporting to include all HIV laboratory tests
WAC 246-201-101 *Notifiable conditions and laboratories*
The final proposed revision removes the required percentages or values of HIV laboratory tests for the test results to be reported to the Department. This revised language would establish that all CD4 and viral load tests are reported to the Department.

Comprehensive (expanded) lab reporting will allow the Department to meet the legislative intent of RCW 70.24. An alternative considered was leaving the existing rule in place. This was rejected as least likely to achieve the objectives of the statute because it would not meet CDC's recommendations for HIV-related laboratory reporting. This proposed rule is the least burdensome alternative because laboratory staff will no longer need to sort HIV laboratory test results for reporting and is the most efficient system to distinguish between and monitor those doing well clinically and those "not in care."

Permit LHJs to retain asymptomatic HIV cases by name
WAC 246-101-520 *Special conditions -- AIDS and HIV*
The final proposed rule permits local name retention of asymptomatic HIV cases and describes the security and confidentiality standards consistent with the Centers for Disease Control and Prevention (CDC) 2006 Security and Confidentiality Guidelines that must be followed for an LHJ to retain asymptomatic HIV case reports by name.

The final proposed rule requires the Department to perform a biennial review of the system security measures for local health jurisdictions that retain asymptomatic case reports by name.

The final proposed rule requires local health officials to report HIV cases to the Department and assist the Department in reascertaining (replace coded identifiers with names) the identities of previously reported cases of asymptomatic HIV infection.

An alternative considered was leaving the existing rule in place for LHJs. This was rejected as least likely to achieve the statutory objectives because it would create two separate retention systems for asymptomatic HIV case reports at the state and local level. The alternative would not produce the most streamlined approach to carry out disease control activities and would not be consistent with other communicable disease reporting practices.

The proposed revision is the least burdensome alternative because Washington State will have a streamlined retention system between the Department and LHJs (that choose to retain asymptomatic HIV cases by name; they are not required to do so through this rule revision) that will provide efficient communicable disease control activities and better understanding of the epidemic locally.

Require the Department to retain asymptomatic HIV cases by name
WAC 246-101-635 *Special condiditions -- AIDS and HIV*

The final proposed rule requires the department to retain asymptomatic HIV cases by name solely for the purpose of complying with the CDC's HIV reporting requirements. This revised section describes the security and confidentiality standards consistent with the CDC's 2006 Security and Confidentiality Guidelines that must be followed by the Department to retain asymptomatic HIV case reports by name.

The state health officer or designee must conduct a biennial review of the system security measures at local health jurisdictions that are maintaing HIV case records by name.

An alternative considered was not to include security and confidentiality standards. This was rejected as least likely to achieve the statutory objectives of RCW 70.24. The CDC only accepts asymptomatic HIV case reports from a confidential name-based retention system. This proposed revision is the least burdensome alternative because the security and confidentiality standards are necessary to remain in compliance with CDC's guidelines. These standards will further reinforce Washington State's excellent track record of no known or reported breaches in our reporting system at the state or local level. It also directly addresses stakeholder concerns and comments on Drafts #1 and #2 of the proposed rule revisions.

A report is due December 2007 to the State Board of Health
WAC 246-101-635 *Special condiditions -- AIDS and HIV*
Final proposed rule states that the state health officer in cooperation with the local health officers will provide a report to the State Board of Health by December 2007 detailing; a) ability of the HIV reporting system to meet surveillance performance standards established by CDC; b) cost of the reporting system to state and local departments; c) reporting systems effect on disease control activities; d) impact of HIV reporting on HIV testing among at-risk persons; and e) availability of anonymous testing in the state.

An alternative considered was not to include the availability of anonymous testing in the 2007 report. The proposed revision is the least burdensome alternative because it addresses stakeholder concerns and comments on Draft #2 of the proposed rule revisions. Anonymous testing is considered a vital HIV testing option that should be available and accessible for individuals that are more hesitant to test confidentially.

E. Determine that the rule does not require those to whom it applies to take an action that violates requirements of another federal or state law.

The rule does not require those to whom it applies to take an action that violates requirements of federal or state law.

F. Determine that the rule does not impose more stringent performance requirements on private entities than on public entities unless required to do so by federal or state law.

The rule does not impose more stringent performance requirements on private entities than on public entities.

G. Determine if the rule differs from any federal regulation or statute applicable to the same activity or subject matter and, if so, determine that the difference is justified by an explicit state statute or by substantial evidence that the difference is necessary.

The rule does not differ from any applicable federal regulation or statute.

H. Demonstrate that the rule has been coordinated, to the maximum extent practicable, with other federal, state, and local laws applicable to the same activity or subject matter.

There are no other applicable laws.